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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,503	03/02/2006	Patrick Stordeur	DECLE35.005APC	6280

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER

WHISENANT, ETHAN C

ART UNIT	PAPER NUMBER
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1634

NOTIFICATION DATE	DELIVERY MODE
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08/15/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary	Application No. 10/563,503	Applicant(s) STORDEUR ET AL.	
	Examiner Ethan Whisenant, Ph.D.	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-33 and 35-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 6, 7, 12, 18, 22-31, 33, 37, 39-41, 46, 52, 56 and 61 is/are rejected.
- 7) ☒ Claim(s) 2, 3, 5, 8, 9, 11, 13-17, 19-21, 32, 35, 36, 38, 42-45, 47-51, 53-55 and 57-60 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

NON-FINAL ACTION

1. The applicant's response (filed 20 MAY 08) to the Office Action has been entered. Following the entry of the claim amendment(s), **Claim(s) 1-9, 11-33, and 35-61** is/are pending. Rejections and/or objections not reiterated from the previous office action are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

35 USC § 112- 2nd Paragraph

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

CLAIM REJECTIONS under 35 USC § 112- 2ND PARAGRAPH

3. **Claim(s) 23-30 and 56** is/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 23 and 56 are indefinite because of the use of a trademark as a limitation therein. If a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of the 35 U.S.C. 112, second paragraph. *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. In fact, the value of a trademark would be lost to the extent that it became descriptive of a product, rather

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than used as an identification of a source or origin of a product. Thus, the use of a trademark or trade name in a claim to identify or describe a material or product would not only render a claim indefinite, but would also constitute an improper use of the trademark or trade name. If a trademark or trade name appears in a claim and is not intended as a limitation in the claim, the question of why it is in the claim should be addressed. Does its presence in the claim cause confusion as to the scope of the claim? If so, the claim should be rejected under 35 U.S.C. 112, second paragraph. See the MPEP at 2173.05(u).

Claims 24-25 are indefinite because there is no nexus between the preamble and the claim steps. For example Claim 25, in its preamble direct to a method which is to accomplish a particular goal. However, none of the claim steps states that this goal is accomplished. For clarity, claimed methods should recite that the purpose of the method has been attained (i.e. provide a nexus between the preamble and the claim steps).

35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

or

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

5. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim Rejections under 35 USC § 102

6. **Claim(s) 1, 4, 12, 18, 22, 33, 37, 39, 46 and 52** is/are rejected under 35 U.S.C. 102(b) as being anticipated by Naegle et al. [US 6,428,962(2002)].

Naegle et al. teach a vessel suitable for accepting a liquid biological sample which comprises all of the limitations recited in Claims 1, 4, 12, 18 and 22 as well as a kit comprising said vessel as recited in Claim 33, 37, 39 and 46. See especially the description of Figure 3 in Column 4, beginning at about line 48. Also, see Example 1 in Column 6. Here the reagent (i.e. the proteinase K solution) in the upper wax barrier is considered the first substance present in said vessel while the reagent in the lower wax barrier (i.e. said container) is the extraction reagent phenol:chloroform:isoamyl alcohol (i.e. a stabilizing agent). As regards Claims 18 and 52, Proteinase K is an protein molecule which may function as an antigen. Finally as regards, Claims 33, 37, 39 and 46 see Column 5, beginning at about line 11.

35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligations under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

CLAIM REJECTIONS UNDER 35 USC § 103

9. **Claim(s) 6-7 and 40-41** is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Naegle et al. [US6,428,962(2002)] in view of Nierman [US 6,793,892 (2004)].

Claim 6 is drawn to an embodiment of the vessel of Claim 1 wherein said vessel comprises one or more areas suitable for puncture by a syringe needle. **Claim 7** is drawn to an embodiment of the vessel of Claim 61 wherein said areas is a re-sealable septum. **Claim 40** is drawn to an embodiment of the kit of Claim 33 wherein said vessel comprises one or more areas suitable for puncture by a syringe needle. **Claim 41** is drawn to an embodiment of the kit of Claim 40 wherein said areas is a re-sealable septum.

Naegle et al. teach a vessel and kit comprising a top/lid/cap which comprises all of the limitations recited in Claims 6-7 and 40-41 except these authors do not teach that their vessel comprises one or more areas suitable for puncture by a syringe needle which area is a re-sealable septum. However, as evidenced by at least Nierman lids/tops/caps which are suitable for puncture by a syringe needle which area is a re-sealable septum were well known in the art at the time of the invention. Therefore, absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of substitute the lids of Nierman for the lid disclosed by Naegle et al. Please note that substitution of one well known method/reagent with known properties for a second well known method/reagent with well known properties would have been *prima facie* obvious to the ordinary artisan at the time of the invention in the absence of an unexpected result. As regards the motivation to make the substitution recited above, the motivation to combine arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making this obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

10. Claim(s) 24, 31 and 61 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Naegle et al. [US6,428,962(2002)] in view of Resnick et al. [US 5,527,669 (1996)].

Claim 24 is drawn to a method of testing RNA components in a stabilized blood sample. **Claim 31** is drawn to a method of testing RNA components in a stabilized blood sample.

Naegle et al. teach a method and kit for isolating and analyzing nucleic acid from a liquid blood sample using a vessel which comprises all of the limitations recited in Claim 24 except these authors do not explicitly teach that RNA present in said blood sample is analyzed. However, as evidenced by at least Resnick et al. it was well known in the art at the time of the invention to analyze RNA present in a liquid biological

samples in order to detect HCV. Therefore, absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to analyze the RNA present in said nucleic acid sample prepared by the method disclosed by Naegle et al. in order to detect the presence of HCV therein.

Claim 61 is drawn to an embodiment of Claim 33 which further comprises one or more oligonucleotides suitable for said testing said mRNA.

Absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to include in the kit taught by Naegle et al. one or more oligonucleotides suitable for testing for a particular mRNA (i.e. the oligos disclosed by Resnick et al. which enable the detection of the mRNA of HCV).

CLAIM OBJECTIONS

11. Claim(s) 48-50 is/are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Note that Claim 48 is dependent on a cancelled claim (i.e. Claim 34). Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. .

CLAIM OBJECTIONS

12. Claim(s) 2-3, 5, 8-9, 11, 13-17, 19-21, 32, 35-36, 38, 42-45, 47, 51, 53-55, 57-60 is /are objected to as being dependent upon a rejected base claim, but would appear to be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

CONCLUSION

13. Claim(s) 1-61 is/are rejected and/or objected to for the reason(s) set forth above.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (571) 272-0754. The examiner can normally be reached Monday-Friday from 8:30 AM - 5:30 PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

The Central Fax number for the USPTO is (571) 273-8300. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

/Ethan Whisenant/
Primary Examiner
Art Unit 1634